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Bristol-Myers Squibb Company

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BRISTOL-MYERS SQUIBB COMPANY, Plaintiff, v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC., Defendants.	)	Civil Action No. 19-cv-18686-MAS-TJB ***Electronically Filed***

FIRST AMENDED COMPLAINT

Plaintiff, Bristol-Myers Squibb Company, by its undersigned attorneys, for their First Amended Complaint against Defendants, Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc., hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Defendants' submissions of an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic

version of Plaintiff's SPRYCEL® (dasatinib) tablets prior to the expiration of United States Patent Nos. 7,491,725, 8,680,103, and/or 8,242,270.

THE PARTIES

2. Plaintiff Bristol-Myers Squibb Company ("BMS") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at Route 206 and Province Line Road, Princeton, New Jersey 08540.

3. On information and belief, Defendant Dr. Reddy's Laboratories Ltd. ("DRL Ltd.") is a corporation organized and existing under the laws of India, having a principal place of business at 8-2-337 Road No. 3, Banjara Hills, Hyderabad, 500034, India.

4. On information and belief, DRL Ltd. controls and directs a wholly owned subsidiary in the United States named Dr. Reddy's Laboratories, Inc. ("DRL Inc."). DRL Inc. is a New Jersey corporation having a principal place of business at 107 College Road East, Princeton, New Jersey 08540.

5. On information and belief, DRL Inc. is acting on behalf of, at the direction, and for the benefit, of DRL Ltd., and is controlled and/or dominated by DRL Ltd. with respect to ANDA No. 213383.

6. DRL Ltd. and DRL Inc. are collectively referred to hereinafter as "DRL."

7. On information and belief, DRL Ltd. is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic drugs, including distributing, selling, and marketing generic drugs throughout the United States, including within the state of New Jersey, through its own actions and through the actions of its agents and subsidiaries, including DRL Inc., from which DRL Ltd. derives a substantial portion of its revenue.

8. On information and belief, DRL Ltd. acted in concert with DRL Inc. to prepare and submit ANDA No. 213383 (the "DRL ANDA") for DRL Ltd.'s 20 mg, 50 mg, 70 mg, 80 mg, 100 mg and 140 mg dasatinib tablets ("DRL ANDA Products").

9. On information and belief, DRL Ltd. acted in concert with DRL Inc. to prepare and submit the DRL ANDA for the DRL ANDA Products, which was done at the direction of, under the control of, and for the direct benefit of DRL Ltd. Following FDA approval of the DRL ANDA, DRL Ltd. will manufacture and supply the approved generic product to DRL Inc., which will then market and sell the products throughout the United States at the direction, under the control, and for the direct benefit of DRL Ltd.

JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*., generally, and 35 U.S.C. § 271(e)(2), specifically, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

11. Venue is proper in this Court because, among other things, DRL Inc. is incorporated in the state of New Jersey and therefore "resides" in this judicial district and/or has committed acts of infringement in this district and has a regular and established place of business in this district. 28 U.S.C. § 1400(b). DRL Ltd. is a foreign corporation not residing in any United States district and may be sued in any judicial district. 28 U.S.C. § 1391(c). Moreover, DRL has litigated previous Hatch-Waxman patent infringement disputes in the District of New Jersey. Additionally, DRL has not contested venue in this case and has asserted counterclaims in this case asserting that venue is proper in this district. *See* Dkt. No. 7 at pp. 3, 10-11.

PERSONAL JURISDICTION OVER DRL LTD.

12. Plaintiff realleges paragraphs 1-11 as if fully set forth herein.

13. On information and belief, DRL Ltd. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

14. This Court has personal jurisdiction over DRL Ltd. because, *inter alia*, DRL Ltd., on information and belief: (1) has substantial, continuous, and systematic contacts with this State, either directly or through at least one of its wholly-owned subsidiaries or agents; (2) intends to market, sell, and/or distribute DRL Ltd. infringing ANDA Products to residents of this State upon approval of ANDA No. 213383, either directly or through at least one of its wholly-owned subsidiaries or agents; (3) enjoys substantial income from sales of its generic pharmaceutical products in this State on its own and through DRL Inc.; and (4) wholly owns DRL Inc., which is incorporated in this State.

15. On information and belief, DRL Ltd. has not contested jurisdiction in New Jersey in one or more prior cases arising out of the filing of its ANDAs, and it has filed counterclaims in such cases. *See, e.g., Celgene Corp. v. Dr. Reddy's Laboratories, Inc. et al.*, C.A. No. 18-11269, Dkt. 26 (D.N.J. Nov. 20, 2018). Moreover, DRL Ltd. has not contested jurisdiction in this case and has filed counterclaims in this case asserting that jurisdiction is proper in this district. *See* Dkt. No. 7 at pp. 3-4, 10-11.

16. Alternatively, to the extent the above facts do not establish personal jurisdiction over DRL Ltd., this Court may exercise jurisdiction over DRL Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiff's claims arise under federal law; (b) DRL Ltd. would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) DRL Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, filing ANDAs with the FDA and manufacturing and selling generic pharmaceutical products that are distributed

throughout the United States, such that this Court's exercise of jurisdiction over DRL Ltd. satisfies due process.

PERSONAL JURISDICTION OVER DRL INC.

17. Plaintiff realleges paragraphs 1-16 as if fully set forth herein.

18. On information and belief, DRL Inc. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

19. This Court has personal jurisdiction over DRL Inc. because, *inter alia*, DRL Inc., on information and belief: (1) is incorporated under the laws of the State of New Jersey, (2) intends to market, sell, or distribute DRL's ANDA Products to residents of this State; (3) makes its generic drug products available in this State; and (4) enjoys substantial income from sales of its generic pharmaceutical products in this State.

20. On information and belief, DRL Inc. has not contested jurisdiction in New Jersey in one or more prior cases arising out of the filing of its ANDAs, and it has filed counterclaims in such cases. *See, e.g., Celgene Corp. v. Dr. Reddy's Laboratories, Inc. et al.*, C.A. No. 18-11269, Dkt. 26 (D.N.J. Nov. 20, 2018). Moreover, DRL Inc. has not contested jurisdiction in this case and has filed counterclaims in this case asserting that jurisdiction is proper in this district. *See* Dkt. No. 7 at pp. 4, 10-11.

BACKGROUND

U.S. PATENT NO. 7,491,725

21. On February 17, 2009, the USPTO duly and legally issued United States Patent No. 7,491,725 ("the '725 patent") entitled "Process for preparing 2-aminothiazole-5-aromatic carboxamides as kinase inhibitors" to inventors Jean Lajeunesse, John D. DiMarco, Michael

Galella, and Ramakrishnan Chidambaram. A true and correct copy of the '725 patent is attached as Exhibit 1. The '725 patent is assigned to BMS.

U.S. PATENT NO. 8,680,103

22. On March 25, 2014, the USPTO duly and legally issued United States Patent No. 8,680,103 ("the '103 patent") entitled "Process for preparing 2-aminothiazole-5-aromatic carboxamides as kinase inhibitors" to inventors Jean Lajeunesse, John D. DiMarco, Michael Galella, and Ramakrishnan Chidambaram. A true and correct copy of the '103 patent is attached as Exhibit 2. The '103 patent is assigned to BMS.

U.S. PATENT NO. 8,242,270

23. On August 14, 2012, the USPTO duly and legally issued United States Patent No. 8,242,270 ("the '270 patent") entitled "Process for preparing 2-aminothiazole-5-aromatic carboxamides as kinase inhibitors" to inventors Jean Lajeunesse, John D. DiMarco, Michael Galella, and Ramakrishnan Chidambaram. A true and correct copy of the '270 patent is attached as Exhibit 3. The '270 patent is assigned to BMS.

SPRYCEL®

24. BMS is the holder of New Drug Application ("NDA") No. 029186 for dasatinib, for oral use, in 20 mg, 50 mg, 70 mg, 80 mg, 100 mg, and 140 mg dosages, which is sold under the trade name SPRYCEL®.

25. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '725 and '103 patents are among the patents listed in the Orange Book with respect to SPRYCEL®.

26. The '725 and '103 patents cover the SPRYCEL® product.

ACTS GIVING RISE TO THIS ACTION

COUNT I—INFRINGEMENT OF THE '725 PATENT

27. Plaintiff realleges paragraphs 1-26 as if fully set forth herein.

28. On information and belief, DRL submitted the DRL ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market the DRL ANDA Products.

29. DRL has represented that the DRL ANDA refers to and relies upon the SPRYCEL® NDA, and contains data that, according to DRL, demonstrate the bioavailability or bioequivalence of the DRL ANDA Products to SPRYCEL®.

30. Plaintiff received a letter from DRL on or about August 23, 2019 stating that DRL had included a certification in the DRL ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '725 and '103 patents are either invalid or will not be infringed by the commercial manufacture, use, or sale of the DRL ANDA Products (the "DRL Paragraph IV Certification"). DRL intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the DRL ANDA Products prior to the expiration of the '725 and '103 patents.

31. DRL has infringed at least one claim of the '725 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the DRL ANDA, by which DRL seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the DRL ANDA Products prior to the expiration of the '725 patent.

32. DRL has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the DRL ANDA Products in the event that the FDA approves the DRL ANDA. Accordingly, an actual and immediate controversy exists regarding DRL's infringement of the '725 patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

33. DRL's manufacture, use, offer to sell, or sale of the DRL ANDA Products in the United States or importation of the DRL ANDA Products into the United States during the term of the '725 patent would further infringe, literally or under the doctrine of equivalents, at least one claim of the '725 patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

34. On information and belief, the DRL ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '725 patent either literally or under the doctrine of equivalents.

35. On information and belief, the use of the DRL ANDA Products constitutes a material part of at least one of the claims of the '725 patent; DRL knows that the DRL ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '725 patent, either literally or under the doctrine of equivalents; and the DRL ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

36. On information and belief, the offering to sell, sale, and/or importation of the DRL ANDA Products would contributorily infringe at least one of the claims of the '725 patent, either literally or under the doctrine of equivalents.

37. On information and belief, DRL had knowledge of the '725 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that they will aid and abet another's direct infringement of at least one of the claims of the '725 patent, either literally or under the doctrine of equivalents.

38. On information and belief, the offering to sell, sale, and/or importation of the DRL ANDA Products by DRL would actively induce infringement of at least one of the claims of the '725 patent, either literally or under the doctrine of equivalents.

39. Plaintiff will be substantially and irreparably harmed if DRL is not enjoined from infringing the '725 patent.

40. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of BMS's reasonable attorney fees.

41. On information and belief, based on the information provided by DRL to date, the factual contentions in paragraph 28-40 have evidentiary support. On information and belief, the factual contentions in paragraphs 28-40 will have further evidentiary support following a reasonable opportunity for further investigation or discovery.

COUNT II—INFRINGEMENT OF THE '103 PATENT

42. Plaintiff realleges paragraphs 1-41 as if fully set forth herein.

43. DRL has infringed at least one claim of the '103 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the DRL ANDA, by which DRL seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the DRL ANDA Products prior to the expiration of the '103 patent.

44. DRL has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the DRL ANDA Products in the event that the FDA approves the DRL ANDA. Accordingly, an actual and immediate controversy exists regarding DRL's infringement of the '103 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

45. DRL's manufacture, use, offer to sell, or sale of the DRL ANDA Products in the United States or importation of the DRL ANDA Products into the United States during the term

of the '103 patent would further infringe, literally or under the doctrine of equivalents, at least one claim of the '103 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

46. On information and belief, the DRL ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '103 patent either literally or under the doctrine of equivalents.

47. On information and belief, the use of the DRL ANDA Products constitutes a material part of at least one of the claims of the '103 patent; DRL knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '103 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

48. On information and belief, the offering to sell, sale, and/or importation of the DRL ANDA Products would contributorily infringe at least one of the claims of the '103 patent, either literally or under the doctrine of equivalents.

49. On information and belief, DRL had knowledge of the '103 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that they will aid and abet another's direct infringement of at least one of the claims of the '103 patent, either literally or under the doctrine of equivalents.

50. On information and belief, the offering to sell, sale, and/or importation of the DRL ANDA Products by DRL would actively induce infringement of at least one of the claims of the '103 patent, either literally or under the doctrine of equivalents.

51. Plaintiff will be substantially and irreparably harmed if DRL is not enjoined from infringing the '103 patent.

52. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of BMS's reasonable attorney fees.

53. On information and belief, based on the information provided by DRL to date, the factual contentions in paragraph 43-52 have evidentiary support. On information and belief, the factual contentions in paragraphs 43-52 will have further evidentiary support following a reasonable opportunity for further investigation or discovery.

COUNT III - INFRINGEMENT OF THE '270 PATENT

54. Plaintiff realleges paragraphs 1-23 as if fully set forth herein.

55. On information and belief, DRL submitted the DRL ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market the DRL ANDA Products.

56. DRL has infringed at least one claim of the '270 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the DRL ANDA, by which DRL seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the DRL ANDA Products prior to the expiration of the '270 patent.

57. DRL has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the DRL ANDA Products in the event that the FDA approves the DRL ANDA. Accordingly, an actual and immediate controversy exists regarding DRL's infringement of the '270 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

58. DRL's manufacture, use, offer to sell, or sale of the DRL ANDA Products in the United States or importation of the DRL ANDA Products into the United States during the term of the '270 patent would further infringe at least one claim of the '270 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

59. On information and belief, the DRL ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly

infringe at least one of the claims of the '270 patent either literally or under the doctrine of equivalents.

60. On information and belief, the use of the DRL ANDA Products constitutes a material part of at least one of the claims of the '270 patent; DRL knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '270 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

61. On information and belief, the offering to sell, sale, and/or importation of the DRL ANDA Products would contributorily infringe at least one of the claims of the '270 patent, either literally or under the doctrine of equivalents.

62. On information and belief, DRL had knowledge of the '270 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that they will aid and abet another's direct infringement of at least one of the claims of the '270 patent, either literally or under the doctrine of equivalents.

63. On information and belief, the offering to sell, sale, and/or importation of the DRL ANDA Products by DRL would actively induce infringement of at least one of the claims of the '270 patent, either literally or under the doctrine of equivalents.

64. Plaintiff will be substantially and irreparably harmed if DRL is not enjoined from infringing the '270 patent.

65. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of BMS's reasonable attorney fees.

66. On information and belief, based on the information provided by DRL to date, the factual contentions in paragraphs 55-65 have evidentiary support. On information and belief, the

factual contentions in paragraphs 55-65 will have further evidentiary support following a reasonable opportunity for further investigation or discovery.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court enter judgment against DRL and for the following relief:

a. A Judgment be entered that DRL has infringed at least one claim of the '725, '103, and/or '270 patents by submitting the DRL ANDA;

b. A Judgment be entered that this case is exceptional, and that Plaintiff is entitled to its reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

c. That DRL, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them be preliminarily and permanently enjoined from: (i) engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs or methods of administering drugs claimed in the '725, '103, and/or '270 patents, and (ii) seeking, obtaining or maintaining approval of ANDAs until the expiration of the '725, '103, and/or '270 patents or such other later time as the Court may determine;

d. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of DRL's ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '725, '103, and/or '270 patents, including any extensions;

e. That Plaintiff be awarded monetary relief if DRL commercially uses, offers to sell, or sells its respective proposed generic versions of SPRYCEL® or any other product that infringes or induces or contributes to the infringement of the '725, '103, and/or '270 patents, within the

United States, prior to the expiration of those patents, including any extensions, and that any such monetary relief be awarded to Plaintiff with prejudgment interest;

f. Costs and expenses in this action; and

g. Such other and further relief as the Court deems just and appropriate.

Dated: February 11, 2020

Respectfully submitted,

s/Liza M. Walsh

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding, nor are there any non-parties known to Plaintiff that should be joined to this action. In addition, I recognize a continuing obligation during the course of this litigation to file and to serve on all other parties and with the Court an amended certification if there is a change in the facts stated in this original certification.

Dated: February 11, 2020

WALSH PIZZI O'REILLY FALANGA LLP

s/Liza M. Walsh
Liza M. Walsh

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiff seeks, *inter alia*, injunctive relief.

Dated: February 11, 2020

WALSH PIZZI O'REILLY FALANGA LLP

s/Liza M. Walsh
Liza M. Walsh